

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

3464. Misbranding of Seconal Sodium capsules, Carbrital capsules, and pentobarbital sodium capsules. U. S. v. Corner Drug Co., Inc. (Donovan Drug Co.), and Charles E. Donovan. Pleas of nolo contendere. Fine of \$250 against corporation and \$50 against individual. (F. D. C. No. 30570. Sample Nos. 80018-K to 80020-K, incl., 80282-K, 80285-K, 80296-K, 80297-K, 80301-K, 80310-K, 80318-K, 80319-K, 80359-K.)

INFORMATION FILED: June 1, 1951, District of Massachusetts, against Corner Drug Co., Inc., trading as the Donovan Drug Co., Boston, Mass., and against Charles E. Donovan, treasurer of the corporation.

INTERSTATE SHIPMENT: From the States of Indiana, Michigan, and New York, into the State of Massachusetts, of quantities of *Seconal Sodium capsules*, *Carbrital capsules*, and *pentobarbital sodium capsules*.

ALLEGED VIOLATION: On or about September 1, 5, 6, 8, 11, 13, 16, 18, and 20, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged capsules contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, in addition, the *Carbrital capsules* contained a substance, carbromal, and the label of the capsules failed to bear the name, and quantity or proportion of such substance and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions "One at bed time" appearing in the labeling of the *Seconal Sodium capsules*, "One capsule at bed time" appearing in the labeling of the *Carbrital capsules*, and "One capsule at night" and "One at night" appearing in the labeling of a number of the repackaged *pentobarbital sodium capsules* were not adequate directions for use, and since the labeling of a portion of the repackaged *pentobarbital sodium capsules* bore no directions for use.

DISPOSITION: June 12, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the corporation and \$50 against the individual.

3465. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Robert L. Mealy (Mason Pharmacy). Plea of guilty. Fine, \$300. (F. D. C. No. 29451. Sample Nos. 60670-K to 60672-K, incl., 60674-K.)

INFORMATION FILED: September 6, 1950, Eastern District of Wisconsin, against Robert L. Mealy, trading as the Mason Pharmacy, Milwaukee, Wis.

ALLEGED SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of *Seconal Sodium capsules* and *Benzedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about September 29 and 30 and October 7 and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement, "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), (1 sale) the *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: June 29, 1951. A plea of guilty having been entered, the court imposed a fine of \$300.

3466. Misbranding of phenobarbital tablets. U. S. v. Renton Ten Cent Drug.
Plea of nolo contendere. Fine, \$1,500. (F. D. C. No. 29428. Sample Nos. 20754-K, 40808-K.)

INFORMATION FILED: January 30, 1951, Western District of Washington, against the Renton Ten Cent Drug, a partnership, Renton, Wash.

ALLEGED VIOLATION: On or about December 4, 1948, the defendant caused to be introduced into interstate commerce at Renton, Wash., for delivery to Omaha, Nebr., a quantity of *phenobarbital tablets* which were misbranded.

In addition, on or about June 2, 1949, while a number of *phenobarbital tablets* were being held for sale at the defendant's store, the defendant caused a number of the tablets to be repacked and sold without a physician's prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the *phenobarbital tablets* failed to bear a label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use since the directions "Half tablet night and morning" and "One tablet as necessary" were not adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: June 7, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$1,500 against the partnership.

3467. Misbranding of Devine's Zina-Ray oil and Devine's inhaler. U. S. v. 434 Bottles, etc. (F. D. C. No. 30884. Sample Nos. 32067-L to 32070-L, incl.)

LIBEL FILED: March 30, 1951, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about January 26 and February 12, 1951, by Devine's Remedies, from Chicago, Ill.